

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA *ex rel.* DAVID M.  
KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M.  
KESTER, STATE OF COLORADO *ex rel.* DAVID M.  
KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M.  
KESTER, STATE OF DELAWARE *ex rel.* DAVID M.  
KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M.  
KESTER, STATE OF FLORIDA *ex rel.* DAVID M.  
KESTER, STATE OF GEORGIA *ex rel.* DAVID M.  
KESTER, STATE OF HAWAII *ex rel.* DAVID M.  
KESTER, STATE OF ILLINOIS *ex rel.* DAVID M.  
KESTER, STATE OF INDIANA *ex rel.* DAVID M.  
KESTER, STATE OF LOUISIANA *ex rel.* DAVID M.  
KESTER, STATE OF MARYLAND *ex rel.* DAVID M.  
KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID  
M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M.  
KESTER, STATE OF MINNESOTA *ex rel.* DAVID M.  
KESTER, STATE OF MONTANA *ex rel.* DAVID M.  
KESTER, STATE OF NEVADA *ex rel.* DAVID M.  
KESTER, STATE OF NEW JERSEY *ex rel.* DAVID M.  
KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M.  
KESTER, STATE OF NEW YORK *ex rel.* DAVID M.  
KESTER, STATE OF NORTH CAROLINA *ex rel.*  
DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.*  
DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.*  
DAVID M. KESTER, STATE OF TENNESSEE *ex rel.*  
DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID  
M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M.  
KESTER, and STATE OF WISCONSIN *ex rel.* DAVID  
M. KESTER,

Plaintiffs and Relator,

-against-

No. 11 Civ. 8196 (CM)

NOVARTIS PHARMACEUTICALS CORPORATION,  
ACCREDO HEALTH GROUP, INC., BIOSCRIP  
CORPORATION, CURASCRIP, INC., CVS  
CAREMARK CORPORATION,

Defendants.

**MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS**

McMahon, J.:

Plaintiff-relator David M. Kester (“the Relator”) filed a sealed *qui tam* action asserting claims arising under the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, and related state laws. The Defendants named in the Complaint include Novartis Pharmaceuticals Corporation (“Novartis”) and certain specialty pharmacies, including CVS Caremark Corporation (“Caremark”), Accredo Health Group, Inc. (“Accredo”), and Curascript, Inc. (“Curascript”) (collectively, the “Pharmacy Defendants”). The Relator alleges that Novartis and these pharmacies violated the FCA and the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), in connection with a kickback scheme.

Pending before the Court are Docket #275, Caremark’s motion to dismiss the Relator’s Third Amended Complaint under Rules 9(b), 12(b)(1), and 12(b)(6), and Docket #277, Accredo’s and Curascript’s motion to dismiss the Relator’s Third Amended Complaint under Rules 12(b)(1) and 12(b)(6). For the reasons discussed below, both motions are granted in part and denied in part.<sup>1</sup>

**BACKGROUND<sup>2</sup>**

**I. The Plaintiffs**

Pursuant to the False Claims Act (“FCA”), private persons known as “relators” may file *qui tam* actions and recover damages on behalf of the United States. *See* 31 U.S.C. § 3730(b). The Relator originally filed this FCA action in November 2011 on behalf of the United States, 26 states, and the District of Columbia.

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<sup>1</sup> This opinion is to be referred to in all future correspondence and papers as “*Novartis VII*.”

<sup>2</sup> The facts are taken from the Relator’s Third Amended Complaint and the Government’s Second Amended Complaint-in-Intervention (which the Relator incorporates by reference).

The Relator filed a Second Amended Complaint on January 30, 2014. Following the Court's decision and order of September 3, 2014, the Relator filed a Third Amended Complaint ("the Relator's Complaint" or "Compl.").

He brings claims against Novartis and the Pharmacy Defendants on behalf of the United States, 26 states, and the District of Columbia. The Relator asserts claims (Counts 1a, 1b, 1c, and 1d)<sup>3</sup> under four subparagraphs of the FCA – 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), and (a)(1)(G). He also asserts claims (Counts 2-28) under 27 different analogues of the FCA, including the parallel false claim statutes in California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

The United States government ("the Government") elected to intervene as a co-plaintiff in this case. On April 23, 2013, the Government filed an Amended Complaint-in-Intervention ("the Government's Complaint") asserting claims against Novartis (but not the Pharmacy Defendants) under the FCA and related state laws. The Government has since filed a Second Amended Complaint (which is the Government's operative complaint).

Eleven states have since intervened as co-plaintiffs against Novartis alone, asserting claims under state law analogues of the FCA.

Generally, the FCA outlaws the submission of a false or fraudulent "claim" for payment (*i.e.*, a request for reimbursement) to the government. *See* 31 U.S.C. § 3729(a)(1). Such claims may be rendered "false" in a variety of ways. In this case, the Relator's FCA claims are predicated on underlying violations of the Anti-Kickback Statute ("AKS"). Under the AKS, it is illegal to

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<sup>3</sup> The Relator asserts all four of his FCA claims as "Count 1." I refer to these claims as Counts 1a, 1b, 1c, and 1d for clarity.

offer a person “remuneration” (*i.e.*, kickbacks) in order to “induce” that person to “recommend” the purchase of a drug covered by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). It is likewise illegal to receive remuneration “in return for . . . recommending purchasing” such drugs. *Id.* at § 1320a-7b(b)(1).

The reader is presumed to be familiar with this Court’s previous orders in this case: denying Novartis’s motion to dismiss the Government’s Complaint pursuant to Rule 9(b), *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242 (S.D.N.Y. 2014) (“*Novartis I*”); granting in part and denying in part Defendants’ motions to dismiss the Relator’s Second Amended Complaint pursuant to Rule 9(b), *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 11 Civ. 8196, 2014 WL 2619014 (S.D.N.Y. June 10, 2014) (“*Novartis II*”); denying the Pharmacy Defendants’ motion for reconsideration of this Court’s order in *Novartis II* (“*Novartis III*”), *see* Docket #216; granting in part and denying in part Novartis’s motion to dismiss the Government’s Complaint pursuant to Rules 12(b)(6) and 9(b), *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196, 2014 WL 4230386 (S.D.N.Y. Aug. 7, 2014) (“*Novartis IV*”); granting in part and denying in part Defendants’ motions to dismiss the Relator’s Second Amended Complaint under Rules 12(b)(1), 12(b)(6), and 9(b), *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196, 2014 WL 4370597 (S.D.N.Y. Sept. 3, 2014) (“*Novartis V*”); and granting in part and denying in part Novartis’s motion to dismiss the intervening states’ complaints under Rules 12(b)(6) and 9(b), *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196, 2014 WL 4401275 (S.D.N.Y. Sept. 4, 2014) (“*Novartis VI*”).

## **II. The Alleged Kickback Scheme**

Defendant Novartis is a pharmaceutical company that develops, manufactures, and markets prescription drugs. It sells these drugs through various avenues, one of which is “specialty” pharmacies which sell drugs that are not available at normal retail pharmacies. (*See* Compl. ¶ 1,



27.) The Relator alleges that Novartis conducted five illegal kickback schemes involving drugs covered by federal health care programs, and that the Pharmacy Defendants participated in those schemes. (Compl. ¶¶ 1, 103-104.)

The Relator, David M. Kester, is a former sales employee of Novartis who discovered that Novartis was engaging in practices that allegedly violated the AKS and the FCA. (Compl. ¶¶ 15-16.) According to the Relator, Novartis realized that certain pharmacies had influence over doctors or patients. So beginning in January 2007 it decided to “leverage” these pharmacies’ influence – it offered them kickbacks in the form of rebates, discounts, and patient referrals to induce them to “recommend” its drugs to doctors or patients. (Compl. ¶ 2.)

The Relator’s Complaint contains a detailed description of the mechanics of the kickback schemes. It alleges that Novartis gave the pharmacies several types of remuneration: “first category rebate[s],” which were volume-based rebates of about 1-3% of all sales of Novartis drugs; “second category rebate[s],” which were performance-based payments depending on quantity sold or market share; and patient referrals, which Novartis controlled through its exclusive distribution networks. (Compl. ¶¶ 87-89.)

When a new patient received a prescription for a specialty medication manufactured by Novartis, the patient would contact a Novartis call center (or “reimbursement hub”). (Compl. ¶ 81.) The reimbursement hub would then steer the patient to one of the specialty pharmacies in its exclusive drug distribution networks. (Compl. ¶¶ 82, 90.)

In return for rebates and patient referrals, the pharmacies (including Caremark, Accredo, and Curascript) allegedly agreed to promote Novartis drugs. Generally, the pharmacies would recommend to doctors and patients that patients switch to Novartis drugs, remain on Novartis drugs (as opposed to discontinuing treatment), or order more refills. The pharmacies implemented “high

touch” programs in which pharmacy staff at call centers would proactively “intervene” – they called patients or doctors under the guise of providing counseling services, but their true goal was to push Novartis drugs. (Compl. ¶¶ 76, 92, 96, 98.) Novartis allegedly provided scripts for the pharmacy staff to use during these calls. (Compl. ¶ 92.) Novartis also encouraged Caremark, Accredo, and Curascript to channel patients from their retail pharmacies to their specialty pharmacies, which had more patient contact and were, thus, better positioned to influence patients. (Compl. ¶ 94.) The Relator alleges that he learned about the pharmacies’ promotional efforts from viewing internal documents and attending Novartis sales meetings and presentations. (Compl. ¶¶ 110-112, 120, 130-131, 136-143.)

Novartis kept track of the pharmacies’ success in promoting its drugs through “scorecarding” – comparing the specialty pharmacies in its networks (including Caremark, Accredo, and Curascript) to their peers. (Compl. ¶¶ 95, 113, 119-120.) Higher performing pharmacies (*i.e.*, pharmacies which sold more Novartis drugs) were rewarded with more rebates and patient referrals. (Compl. ¶ 89, 95.) The Relator claims that he attended meetings in which these scorecards were discussed. (Compl. ¶¶ 120, 125-126.)

Novartis referred to this system of offering pharmacies rebates and referrals in exchange for their promotional efforts as the “specialty pharmacy model.” (Compl. ¶¶ 112, 125, 139.)

The Relator alleges that, by implementing the “specialty pharmacy model,” Novartis orchestrated kickback schemes for five of its drugs – Myfortic, Exjade, Gleevec, Tasigna, and TOBI. The model was first used to sell Exjade and Gleevec in 2007. It was later “export[ed]” to the sales teams for Tasigna, TOBI, and Myfortic. (Compl. ¶¶ 104, 125, 149.) Caremark, Accredo, and Curascript allegedly participated in the Gleevec, Tasigna, and TOBI schemes. Accredo also participated in the Exjade scheme. (Compl. ¶¶ 31, 36, 40, 101-151.)

The Relator alleges that the “specialty pharmacy model” harmed patients because it compromised the pharmacists’ ethical duty to recommend the safest, most effective drug; some of the drugs involved in the schemes had serious side effects. The Relator further alleges that the pharmacy staff members at the call centers lacked the requisite training and education to make therapeutic recommendations. (Compl. ¶¶ 97-98, 115-116.) Finally, Novartis induced the pharmacists to recommend drugs that were more costly for patients than the alternatives. (Compl. ¶ 98.)

The Relator’s Complaint incorporates by reference the detailed allegations contained in the Government’s Complaint relating to the involvement of Novartis and six other pharmacies (which are not named as defendants in the Relator’s Complaint) in the Myfortic and Exjade schemes. (Compl. ¶¶ 103, 145.) Those allegations are described in *Novartis I*. See 23 F. Supp. 3d at 246-50.

### **III. The Relator’s Causes of Action**

The Relator alleges that these kickback schemes caused the Pharmacy Defendants (and the other pharmacies involved in the schemes) to submit “false” claims for the reimbursement of Novartis drugs to several government programs: Medicare, Medicaid, and the Department of Defense TRICARE program (formerly known as “CHAMPUS”).<sup>4</sup> (See Compl. ¶ 19.)

The Relator contends that compliance with the AKS is a precondition to payment of claims submitted to government programs. (Compl. ¶ 47.) The pharmacies that participated in the kickback schemes (including the Pharmacy Defendants) allegedly made both “express” and “implied” certifications (*i.e.*, representations) of compliance with the AKS in connection with the

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<sup>4</sup> Earlier versions of the Complaint also alleged the Pharmacy Defendants submitted false claims under the Federal Employees Health Benefits Plan (“FEHB”). (See Relator’s Second Amended Complaint ¶ 19.) The Court dismissed those claims in *Novartis V* because FEHB is exempt from AKS requirements. See *Novartis V*, 2014 WL 4370597, at \*25.

claims for Novartis drugs that they submitted to government programs. (Compl. ¶¶ 24, 48, 49a, 49b, 50-51, 102.)<sup>5</sup> Because those pharmacies were in fact receiving kickbacks in violation of the AKS, the Relator argues, the certifications were “false.” Accordingly, every claim for Novartis drugs that was submitted while those certifications were in effect was “false” within the meaning of the FCA, since the pharmacies’ AKS violations tainted those claims and rendered them ineligible for reimbursement.

Because the kickback schemes orchestrated by Novartis allegedly caused the Pharmacy Defendants to submit “false” claims to government programs, the Relator asserts several causes of action against Novartis and the Pharmacy Defendants under the False Claims Act.

Counts 1a, 1b, 1c, and 1d assert that the defendants violated four FCA subparagraphs by: (a) “knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1)(A) (count 1a); (b) “knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim,” *id.* § 3729(a)(1)(B) (count 1b); (c) “conspir[ing] to commit a violation of” another subparagraph of the FCA, *id.* § 3729(a)(1)(C) (count 1c); and (d) “knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government,” *id.* § 3729(a)(1)(G) (count 1d).<sup>6</sup>

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<sup>5</sup> The Complaint includes two paragraphs numbered 49. I refer to those paragraphs sequentially as paragraphs 49a and 49b.

<sup>6</sup> The Relator also mentions the versions of these FCA subparagraphs that were in effect prior to the enactment of the Fraud Enforcement and Recovery Act of 2009, which amended the FCA. That statutory amendment is explained in *Novartis I*. See 23 F. Supp. 3d at 250-51. The statutory changes do not affect the outcomes of these motions.



The Relator also asserts claims (counts 2-28) under 27 analogues of the FCA generally, without identifying a specific provisions of any of those statutes. These claims pertain to claims for repayment submitted to state and District of Columbia Medicaid programs.

#### **IV. Procedural History**

In *Novartis II*, the Court granted in part and denied in part the Defendants' motions to dismiss counts 1a and 1b of the Relator's Complaint pursuant to Rule 9(b). I concluded that the Relator's Complaint failed to plead the submission of false claims for Gleevec, Tasigna, and TOBI with particularity.

However, I denied the Defendants' motions to dismiss counts 1a and 1b insofar as they concerned the Exjade and Myfortic schemes until I could rule on the viability of the Relator's theory of claim "falsity." See *Novartis II*, 2014 WL 2619014, at \*7, 9-10. The Court has since concluded that the "false certification" theory of claim falsity asserted by both the Relator and the Government in this case is legally viable, for the reasons discussed at length in *Novartis IV*. See 2014 WL 4230386, at \*3-10. I also denied the Defendants' motions to dismiss the Relator's claims under the state analogues to the FCA (Counts 2-28). See 2014 WL 2619014, at \*11.

The Pharmacy Defendants then moved for reconsideration of the Court's decision in *Novartis II*. I denied that motion because they did not point to "an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." *Novartis III* at 2 (quoting *Doe v. N.Y.C. Dep't. of Soc. Servs.*, 709 F.2d 782, 789 (2d Cir. 1983)).

In *Novartis V*, the Court granted in part and denied in part Defendants' motions to dismiss the Relator's Complaint pursuant to Rules 9(b), 12(b)(1), and 12(b)(6).

Pursuant to the public disclosure bar, 31 U.S.C. § 3730(e)(4), I dismissed count 1 as against Caremark for claims submitted to government healthcare programs prior to March 2009. (The

Relator has since waived count 1 as against Caremark for false claims submitted before March 23, 2010.)

I also dismissed all counts in the Relator's Complaint insofar as they concerned claims submitted to the Federal Employees Health Benefits Program ("FEHB") (with prejudice), and insofar as they concerned claims submitted to TRICARE and Medicaid programs other than those of New York, Illinois, Michigan, and Florida prior to March 23, 2010 (without prejudice).

The Relator's Third Amended Complaint seeks to remedy the deficiencies identified in *Novartis II* and *Novartis IV*. The Relator has included more detailed allegations of false certifications under TRICARE and most state Medicaid programs. The Relator has also included a sample of allegedly false claims submitted under state Medicaid programs in an attempt to plead his claims with particularity.

The Pharmacy Defendants have now moved to dismiss parts of the Relator's Complaint under Rules 9(b), 12(b)(1), and 12(b)(6). Those motions are fully briefed and ready for decision.

## **DISCUSSION**

### **I. Standard**

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the Complaint as true, and draw all reasonable inferences in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007).

However, to survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing

*Twombly*, 550 U.S. at 556). “While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal quotations, citations, and alterations omitted). Thus, unless a plaintiff’s well-pleaded allegations have “nudged [its] claims across the line from conceivable to plausible, [the plaintiff’s] complaint must be dismissed.” *Id.* at 570; *see also Iqbal*, 556 U.S. at 680.

This liberal pleading standard is modified by Rule 9(b), which requires a plaintiff asserting fraud claims to meet a heightened pleading standard. While Rule 8(a) usually requires only a “short and plain statement of the claim showing that the pleader is entitled to relief,” FED. R. CIV. P. 8(a)(2), a plaintiff asserting fraud must “state with particularity the circumstances constituting fraud or mistake.” FED. R. CIV. P. 9(b). Rule 9(b) applies to claims brought under the FCA and its state law analogues. *See Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995) (per curiam); *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04 Civ. 704, 2009 WL 1456582, at \*4 (E.D.N.Y. May 22, 2009).

To survive a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff “must allege facts that affirmatively and plausibly suggest” that the Court has jurisdiction. *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011) (per curiam). The plaintiff bears the burden of establishing by a preponderance of the evidence that subject-matter jurisdiction exists over his complaint. *See Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). If the defendants challenge only the legal sufficiency of the jurisdictional allegations, “the court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of plaintiff.” *Robinson v. Gov’t of Malaysia*, 269 F.3d 133, 140 (2d Cir. 2001)

(internal citations and quotation marks omitted). Where the defendants place jurisdictional facts in dispute, however, the court may properly consider “evidence relevant to the jurisdictional question [that] is before the court.” *Id.* at 140; *see also Amidax*, 671 F.3d at 145.

To prevail on a motion for reconsideration, the movant must demonstrate “an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice.” *See Doe v. N.Y.C. Dep’t of Soc. Servs.*, 709 F.2d 782, 789 (2d Cir. 1983). The decision to grant or deny the motion for reconsideration is within the sound discretion of the district court, especially when there has been no appellate review of the prior decision. *Mina Invest. Holdings Ltd. v. Lefkowitz*, 184 F.R.D. 245, 250 (S.D.N.Y. 1999).

The Court’s review “is narrow and applies only to already-considered issues; new arguments and issues are not to be considered.” *See Morales v. Quintiles Transnat’l Corp.*, 25 F. Supp. 2d 369, 372 (S.D.N.Y. 1998). A motion for reconsideration “is not a substitute for appeal and may be granted only where the Court has overlooked matters or controlling decisions which might have materially influenced the earlier decision.” *See id.* (internal citations and quotation marks omitted).

## **II. The Public Disclosure Bar Does Not Require Dismissal of Most of Relator’s Claims**

The “public disclosure bar” (31 U.S.C. § 3730(e)(4)) requires a court to dismiss a *qui tam* suit (as opposed to a suit brought by the government) where the defendant was publicly accused of similar wrongdoing prior to the filing of the relator’s complaint. The purpose of this impediment to suit is to prevent “parasitic lawsuits by those who learn of the fraud through public channels and seek remuneration although they contributed nothing to the exposure of the fraud.” *U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992).



In *Novartis V*, the Court held that the public disclosure bar is jurisdictional, so if the public disclosure bar applies to Relator's claims, then the Court lacks subject matter jurisdiction to hear them. *Novartis V*, 2014 WL 4370597, at \*8.

Under § 3730(e)(4)(A), there is a two-prong test for determining whether the public disclosure bar applies: (1) whether the allegations in the complaint are "substantially similar" to allegations contained in prior "public disclosures," and, if so, (2) whether the suit may nonetheless go forward because the relator is an "original source" of the information underlying his allegations of fraud. See *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 296-97 (S.D.N.Y. 2013); *U.S. ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 09 Civ. 710, 2011 WL 167246, at \*6 (N.D.N.Y. Jan. 19, 2011); see also *Novartis V*, 2014 WL 4370597, at \*8-9.

In performing the "substantially similar" analysis, a court may only consider sources that are enumerated as "public disclosure[s]" in the "exclusive list" furnished by the FCA. *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 104 (2d Cir. 2010) *rev'd on other grounds*, 131 S. Ct. 1885 (2011). In the pre-2010 version of the statute, the enumerated sources included: "public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media." 31 U.S.C. § 3730(e)(4)(A) (2006). The term "news media" includes not only news articles, but also disclosures directed to "smaller" or "professionally specialized" reader bases. *Ping Chen*, 966 F. Supp. 2d at 297 (internal citations and quotation marks omitted).

In 2010, the False Claims Act was amended in ways that altered the scope of the public disclosure bar. Accusations of wrongdoing contained in state court complaints qualified as "public disclosures" under the pre-2010 version of the False Claims Act. See *U.S. v. N.Y.C. Dep't of Hous.*,

*Preservation & Dev.*, No. 09 Civ. 6547, 2012 WL 4017338, at \*4 (S.D.N.Y. Sept. 10, 2012). However, after the 2010 amendment, the list of enumerated sources limited the types of “hearings” in which such disclosures can be made to “*Federal* criminal, civil, or administrative hearing[s] in which the Government or its agent is a party.” 31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis added). Thus, from and after the effective date of the 2010 amendment, a court may consider federal court filings, but not state court filings, when it decides whether “substantially similar” facts were disclosed prior to the bringing of a *qui tam* relator’s lawsuit.

The standard for determining whether a relator’s allegations are “substantially similar” to prior public disclosures is whether the disclosures in question exposed “all the *essential elements* of the alleged fraud.” *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 437 F. App’x 13, 17 (2d Cir. 2011) (summary order) (emphasis added). In *United States ex rel. Springfield Terminal Railway v. Quinn*, 14 F.3d 645 (D.C. Cir. 1994), the D.C. Circuit explained that a public disclosure does not bar a *qui tam* case unless the public disclosure included “the allegation of fraud” itself or “the critical elements of the fraudulent transaction,” from which an inference of fraud could be raised:

[I]f  $X + Y = Z$ ,  $Z$  represents the *allegation* of fraud and  $X$  and  $Y$  represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of  $X$  and  $Y$  must be revealed, from which readers or listeners may infer  $Z$ , *i.e.*, the conclusion that fraud has been committed . . . Congress sought to prohibit *qui tam* actions *only* when either the allegation of fraud or the critical elements of the fraudulent transaction themselves were in the public domain . . . *Id.* at 654 (emphasis in original).

In other words, the question is “whether the information conveyed [in the public disclosures] could have formed the basis for a governmental decision on prosecution, or could at least have alerted law-enforcement authorities to the likelihood of wrongdoing.” *Id.* (quoting *U.S. ex rel. Joseph v. Cannon*, 642 F.2d 1373, 1377 (D.C. Cir. 1981)). If so, then the allegations in the relator’s complaint are “substantially similar” to the publicly disclosed allegations of wrongdoing, and the first prong of the public disclosure bar test is met.

In order to bar claims against a particular defendant, the public disclosures relating to the fraud must either explicitly identify that defendant as a participant in the alleged scheme, or provide enough information about the participants in the scheme such that the defendant is identifiable. *See U.S. ex rel. Baltazar v. Warden*, 635 F.3d 866, 867-68 (7th Cir. 2011); *U.S. ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 571 (10th Cir. 1995); *Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 566 (11th Cir. 1994) (per curiam). In other words, the public disclosures must “set the government squarely on the trail” of a specific and identifiable defendant’s participation in the fraud. *In re Natural Gas Royalties*, 562 F.3d 1032, 1041 (10th Cir. 2009) (quoting *Fine*, 70 F.3d at 571).

**A. The Court Will Not Reconsider Its Holding that the Public Disclosure Bar Applies As Against Caremark Only for False Claims Submitted Before March 23, 2010**

In *Novartis V*, Caremark argued that the Relator’s claims against it should be dismissed under the public disclosure bar because substantially similar allegations had been made against it in a complaint filed in Michigan state court. *See Complaint, Cox ex rel. Michigan v. Caremark Rx, L.L.C.*, No. 08-187-CP (Mich. Cir. Ct. Feb. 13, 2008) (“Michigan Complaint”). The Michigan Complaint alleged that between 1997 and 2008 Caremark received rebates from drug manufacturers in return for persuading doctors and patients to switch to those manufacturers’ drugs. Ultimately, Caremark settled with Michigan and the other states that had investigated its drug-switching operation. As part of the settlement, Caremark entered into a consent decree. *See Final Judgment and Consent Degree, Cox ex rel. Michigan v. Caremark Rx, L.L.C.*, No. 08-187-CP (Mich. Cir. Ct. Feb. 14, 2008) (“Michigan Consent Decree”).

The Court found in its earlier opinion that the allegations against Caremark and Caremark’s settlement with the states were both widely reported in the news media. *Novartis V*, 2014 WL

4370597, at \*11. Caremark correctly points out that it also disclosed the existence of these settlements in its 10-K reports as recently as February 8, 2013.

The Court agreed with Caremark that the Michigan Complaint and the Relator's Complaint alleged "virtually identical" misconduct. *Id.* at \*12. "As concerns Caremark, the crux of the fraudulent kickback scheme alleged by the Relator is the *quid pro quo* arrangement between Caremark and Novartis: Caremark accepted kickbacks from Novartis in exchange for promoting certain drugs to doctors and patients under the guise of providing independent pharmacy services." *Id.* The Michigan Complaint described essentially the same scheme, including drug-switching and the use of unlawful rebates. *Id.* at \*12-13. The Court found that the two sets of allegations were substantially similar even though the Relator had alleged additional details about Novartis's role in the scheme, the drugs involved, and the roles of other pharmacies. *Id.*

The tricky issue in *Novartis V* was timing. The Relator's Complaint alleged that Caremark's kickback scheme began in 2007 and continued through the present, whereas the Michigan Complaint described a kickback scheme lasting from 1997 to 2008. The Court noted that "the record [in *Novartis V*] contain[ed] no evidence of any public disclosure from and after February 2008 that revealed Caremark's *continued* participation in a drug switching scheme from 2008 to present – a long six-year time period after Caremark settled with the states." *Id.* at \*13 (emphasis in original). That remains true. Caremark still has not pointed to any public disclosures alleging that Caremark engaged in drug switching after 2008.

"The question then becomes: on what date does publicly disclosed information reach the end of its shelf life?" *Id.* at \*16. On the one hand, it would have been absurd to suggest that the states' allegations against Caremark became stale the day after the Michigan Consent Decree was executed. "[A]n extensive fraudulent scheme [that] occurred on February 14 strongly indicate[s]



that the scheme is still taking place on February 15 and February 16.” *Id.* On the other hand, old allegations do lose inculpatory value. At some point, prior allegations of fraud no longer suggest ongoing fraud. *Id.* at \*15-16. Stale allegations do not necessarily “set the government squarely on the trail” of a specific defendant’s participation in a more recent fraud, *In re Natural Gas Royalties*, 562 F.3d 1032, 1041 (10th Cir. 2009) (internal citations and quotation marks omitted), and are therefore not “substantially similar” fresh fraud allegations.

Ultimately, the Court found that March 23, 2010 (the effective date of the 2010 False Claims Act amendment) was the appropriate “sell by” date for the allegations in the state lawsuits, and ruled that the Relator’s suit alleging fraudulent conduct after that date was not subject to dismissal because of the public disclosure bar. By contrast, I ruled that allegations concerning conduct prior to that date (i.e., between 2007 and March 23, 2010) were subject to dismissal under the public disclosure bar, unless Relator could show that he was the “original source” of the information. *Id.* at \*16. March 23, 2010 was a logical date because, after March 23, 2010, state court filings no longer trigger the public disclosure bar. *Id.*

Caremark urges reconsideration of that holding. It argues that the allegations in the Michigan Complaint indicated ongoing fraud through 2013. Caremark does not support its position with any new evidence or case law, and that would be difficult, since the Michigan Complaint was not amended to allege misconduct continuing into 2013 – quite the contrary, the case was closed on February 14, 2008. Instead, Caremark notes that the Michigan Consent Decree required Caremark to “provide to the Attorney General of each Participating State a certification . . . certifying Caremark’s compliance with th[e] Consent Decree,” and an annual “report showing the manner in which Caremark has complied with the Consent Decree” until February 14, 2013 – five years after the Consent Decree was ratified. Michigan Consent Decree at 51. According to

Caremark, those ongoing obligations put the government squarely on its trail not through March 23, 2010, but through February 14, 2013, when the certification requirement ended.

The Court is not persuaded by Caremark's argument.

In *Novartis V*, I explained that "the Relator's allegation from February 2008 on is essentially that Caremark failed to comply with the settlement." 2014 WL 4370597, at \*15. Caremark's misconduct immediately before it settled with the states supported a reasonable inference of misconduct two days after the settlement. But the same inference is not reasonable two years after the settlement. *Id.* at \*16. One cannot infer ongoing fraud in perpetuity from the mere existence of a settlement that resolved allegations of past fraud. That is true whether or not the settlement imposes continuing obligations.

The certification requirement contained in the Michigan Consent Decree does not alter any of that analysis. By providing a certification that it complied with the Michigan Consent Decree, and explaining how it complied, Caremark did not alert the government that it was failing to comply. Far from setting the government "squarely on the trail" of ongoing fraud, *In re Natural Gas Royalties*, 562 F.3d at 1041 (internal citations and quotation marks omitted), Caremark's action would be more likely to put the government's mind at ease.

I therefore adhere to my ruling in *Novartis V* that the Relator's allegations arising after March 23, 2010 are not "substantially similar" to those raised in the Michigan Complaint and Michigan Consent Decree. I thus have no need to consider whether the Relator was an "original source" of those allegations.

I will, however, grant Caremark's motion to the extent of dismissing Relator's claims insofar as they concern allegedly false claims submitted before March 23, 2010 in the following states: California, Connecticut, Delaware, the District of Columbia, Florida, Illinois, Louisiana,

Massachusetts, Michigan, Nevada, New Mexico, North Carolina, Tennessee, Texas, and Virginia.<sup>7</sup> I have reviewed the statutes in question, and all of them contain public disclosure bars that operate similarly to the federal bar. All of them prohibit a Relator from bringing claims based on allegations that are substantially similar to allegations previously disclosed in news media. I found in *Novartis V* that the Michigan Complaint and Michigan Consent Decree were widely reported in the media. *Novartis V*, 2014 WL 4370597, at \*11. I see no reason why the public disclosure bars in the laws of the several states and the District of Columbia would operate any differently with respect to pre-March 2010 claims than does the federal FCA. The Relator's claims under the laws of those states and the District of Columbia are therefore dismissed with prejudice insofar as they concern allegedly false claims submitted before March 23, 2010.

**B. The Motion to Dismiss Relator's Claims Against Accredo and Curascript Are Not Subject to Dismissal Under the Public Disclosure Bar Is Denied.**

In *Novartis V*, the Court rejected Accredo's and Curascript's attempts to invoke the public disclosure bar. Both defendants cited news articles about pharmaceutical pricing practices, but those news articles "contained no suggestion of wrongdoing" and "[t]hey did not allege that drug companies and pharmacies were engaged in a fraudulent scheme of any sort, let alone a *quid pro quo* arrangement in which pharmacies promoted drugs to doctors and patients in exchange for rebates – the crux of the Relator's allegations." *Novartis V*, 2014 WL 4370597, at \*20. Thus, the "allegations" contained in those news articles were not "substantially similar" to those made by the Relator, and the public disclosure bar did not apply. *Id.*

Accredo and Curascript have belatedly brought to the Court's attention earlier lawsuits against their parent companies that are quite similar to the states' lawsuits against Caremark. This

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<sup>7</sup> Caremark does not address the Relator's claims under Colorado, Georgia, Hawaii, Indiana, Maryland, Minnesota, Montana, New Jersey, New York, Oklahoma, Rhode Island, and Wisconsin statutes.

new evidence might give the Court pause – if it contained any reference to Accredo and Curascript. As it does not, revealing the existence of these lawsuits gets those defendants exactly nowhere.

Curascript points to a multi-state investigation, complaint, and settlement with its current parent company, Express Scripts. Curascript has provided a copy of a petition and settlement filed in Tennessee State Court. *See* Petition, No. 08C1690, *State of Tenn. ex rel. Cooper v. Express Scripts, Inc.* (Circuit Ct. Tenn. May 29, 2008) (“Tennessee Petition”); Assurance of Voluntary Compliance and Discontinuance, *State of Tenn. ex rel. Cooper v. Express Scripts, Inc.*, No. 08C1690 (Circuit Ct. Tenn. May 29, 2008) (“Tennessee Settlement”). Similar documents were filed in other state courts.

That lawsuit alleged that Express Scripts operated a “[d]rug [i]nterchange” programs between 1997 and 2008. Tennessee Settlement at 5. In return for manufacturer rebates, Express Scripts solicited physicians and patients to substitute manufacturer drugs for generic or competitor drugs. Tennessee Petition ¶ 2(B). Express Scripts allegedly operated these programs without disclosing to doctors or patients that it had rebate agreements with the manufacturers whose drugs it was pushing. Tennessee Petition ¶ 2(C).

Like the Michigan Complaint against Caremark, the Tennessee Petition against Express Scripts disclosed all the “essential elements” of the fraud alleged in the Relator’s Complaint: that Express Scripts “accepted kickbacks . . . in exchange for promoting certain drugs to doctors and patients,” “that the kickbacks took various forms, including . . . rebates,” “that [Express Scripts] employees promoted [manufacturer] drugs by recommending to doctors and patients that patients switch to [manufacturer] drugs,” and that the “recommendations took the form of phone calls and



other communications.” *Novartis V*, 2014 WL 4370597, at \*12.<sup>8</sup> Curascript argues that these earlier allegations against Express Scripts require the Court to dismiss the Relator’s claims against it at least for conduct before March 23, 2010.

For its part, Accredo points to a False Claims Act suit against Medco, its current parent corporation. That lawsuit, which settled in 2006, involved a variety of fraudulent conduct between 1995 and 2004. The complaint in that action, which Accredo has submitted here along with its motion to dismiss, alleged that Medco induced physicians to switch patient medications as part of an “interchange” program in exchange for rebates from drug manufacturers. *See* Complaint ¶¶ 2-3, 31, *U.S. ex rel. Piacentile v. Merck & Co., Inc.*, No. 00 Civ. 737 (E.D. Pa. Feb. 10, 2000) (“Pennsylvania Complaint”). The settlement agreement between Medco, the relators, and the Government stated that Medco received improper payments, including rebates, in exchange for promoting manufacturer drugs and inducing patients to switch from generic competitors to higher-priced drugs. *See* Settlement Agreement and Mutual Release §§ II.F.2.m, II.F.4, *U.S. ex rel. Piacentile v. Merck & Co., Inc.*, No. 00 Civ. 737 (E.D. Pa.) (“Pennsylvania Settlement”).

I agree with Accredo that the allegations disclosed in the lawsuit against Medco include all the “essential elements” of the fraud alleged by the Relator. *See Novartis V*, 2014 WL 4370597, at \*12. The Relator does not even contest that conclusion.

Accredo argues that the public disclosure bar requires dismissal of the Relator’s claims against it, not only through March 23, 2010, but all the way to October 2011. That is because a Corporate Integrity Agreement that Medco signed as part of the settlement required Medco to report on its compliance annually, and to conduct an outside review to monitor its compliance with

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<sup>8</sup> The Relator’s attempt to distinguish the allegations in these two lawsuits is entirely unconvincing. In *Novartis V*, the Relator pressed exactly the same distinctions between his lawsuit and the lawsuit against Caremark. *Compare* Relator Opp. at 10, *with Novartis V*, 2014 WL 4370597, at \*12. Those distinctions did not defeat a finding of “substantial similarity” there, and they do not do so here.

the settlement, through October 2011. Meron Decl. Ex. 8 (“Medco Corporate Integrity Agreement”) at 25-27. Furthermore, Accredo notes that, unlike the allegations against Caremark in the Michigan Complaint, the allegations against Medco were made in a federal lawsuit. Thus, Accredo argues that March 23, 2010 – the date on which state court filings ceased to trigger the public disclosure bar – is not a sensible “sell-by” date for the allegations against Medco.

The obvious problem with Accredo’s and Curascript’s arguments is that these lawsuits named their parent companies – but not Accredo and Curascript – as defendants. The lawsuits, whether state or federal, do not accuse either Accredo or Curascript of any wrongdoing whatsoever. Accredo and Curascript cite complaints, settlement agreements, and news reports of the suits against Medco and Express Script. None of those documents explicitly identifies Accredo or Curascript as a participant in the schemes alleged in the prior cases.

As I explained in *Novartis V*, “In order to bar claims against a particular defendant, the public disclosures relating to the fraud must either explicitly identify that defendant as a participant in the alleged scheme, or provide enough information about the participants in the scheme such that the defendant is identifiable.” 2014 WL 4370597, at \*10. The question is therefore whether the disclosures cited by Accredo and Curascript “provide enough information about the participants in the scheme such that the defendant is identifiable” as a participant. 2014 WL 4370597, at \*10. Viewing the allegations here and in the earlier lawsuits as a whole, I do not believe those disclosures provide enough information.

First, none of the news articles, settlement agreements, or complaints cited by Accredo and Curascript identifies which alleged misconduct (if any) was committed by subsidiaries of Express Scripts and Medco. It appears from the documents filed in both cases that both Medco and Express Scripts – the parent companies – may have been directly involved in drug switching. *See Tennessee*

Petition ¶ 2(A), (C); Pennsylvania Settlement § II.A. So it is possible that Medco and Express Scripts subsidiaries – though governed by the settlements – were not guilty of any wrongdoing.

Furthermore, in the case of Medco, even if its subsidiaries had committed wrongdoing, they may not have engaged in drug switching. That is because the Medco settlement alleges other misconduct, including “Excluding prescriptions received toward the end of each month from the monthly turnaround reports,” “Cancelling prescriptions as ‘out of stock’ . . . when the drug . . . was not out of stock,” and “restock[ing] and reus[ing] returned medication.” Pennsylvania Settlement § II.F.2.

Finally, even if one could reasonably assume that some Medco or Express Scripts subsidiaries were involved in a drug switching scheme, it is not clear which subsidiaries were involved. In fact, the closest any document comes to providing that information is the Medco Settlement, *which lists numerous subsidiaries other than Accredo* that Medco used to operate its mail order pharmacy. Pennsylvania Settlement § II.A. If anything, the absence of Accredo’s name from the list of tainted subsidiaries suggests that Accredo (a relatively recently acquired subsidiary) was not involved in Medco’s kickback scheme. None of the documents submitted in connection with the Express Scripts settlement names particular subsidiaries in any capacity – and certainly none mentions Curascript.

Accredo and Curascript respond that they became subsidiaries of Medco and Express Scripts before the settlement were signed and note that the settlements bound all subsidiaries as well as their parent companies (Tennessee Settlement at 7; Pennsylvania Settlement § II.A). But the fact that Medco and Express Scripts agreed that their subsidiaries would be bound by the settlements – a common enough term in any corporate settlement – does not establish that the subsidiaries, which are independent corporations, were involved in the wrongdoing that was the

subject of the lawsuits in the first place. In Accredo's case, that would have been impossible, because Accredo was not acquired by Medco until 2005, Accredo & Curascript Mem. at 7 n.4 – which, while before the settlement with Medco was signed, was after the misconduct described in the settlement occurred. Pennsylvania Settlement § F (“The United States contends that . . . Medco . . . engag[ed] in the following conduct during the period from January 1, 1995, through December 31, 2004.”) At no time prior to December 31, 2004 was Accredo a subsidiary of Medco. Accredo did establish a “strategic alliance” with Medco some time in 2004, Accredo & Curascript Reply Mem. at 3, but Accredo does not describe exactly what the alliance entailed, and the settlement documents do not purport to bind “strategic allies” of Medco.

The period of alleged misconduct governed by the Express Scripts settlement with the State of Tennessee ran from 1997 to 2008. Tennessee Settlement at 5. Express Scripts acquired Curascript in 2004, seven years into the time period of the kickback scheme but well before the settlement was reached. However, while this presents a closer case, the complete absence of any mention of Curascript from the Tennessee Settlement documents ultimately dooms Curascript's “substantial similarity” argument. Curascript has made no showing that the corporate veil between it and its post-2004 parent should be torn asunder; in the absence of such a showing one presumes the separate existence and separate conduct of parent and subsidiary. *See United States v. Bestfoods*, 524 U.S. 51, 61 (1998). Nothing in the Tennessee lawsuit documents or the settlement explains how *Curascript* perpetrated the “essential elements” of the kickback scheme described by the Relator, which means the evidence provided by Curascript falls well short of “provid[ing] enough information . . . such that the defendant[s are] identifiable.” 2014 WL 4370597, at \*10.

The Court has not been able to locate any cases involving this precise issue – the effect of publicly disclosed allegations against a parent corporation on a False Claims Act suit against a



subsidiary. But other public disclosure bar cases provide some support for the Court's holding. In *Cooper v. Blue Cross & Blue Shield of Florida, Inc.*, 19 F.3d 562, 564-65 (11th Cir. 1994) (per curiam), the relator alleged that Blue Cross and Blue Shield of Florida ("BCBSF") had fraudulently billed Medicare for claims relating to "working aged" individuals, who had coverage under Medicare and another healthcare plan. By law, BCBSF was supposed to pay those claims first as the primary insurer, and bill Medicare as the secondary insurer. In fact, BCBSF had done the opposite. *Id.*

BCBSF argued that substantially similar allegations of Medicare fraud had been disclosed [1] in a 1998 GAO report that "discusse[d] widespread [Medicare Secondary Payer] fraud and name[d] other insurance companies," [2] in newspapers articles about Medicare fraud, and [3] in and a prior lawsuit suit against Blue Cross Blue Shield of Georgia. *Id.* at 566. The Eleventh Circuit held that all of those allegations, which revealed "widespread – but not universal – fraud in an industry," *id.*, did not sufficiently identify BCBSF as a perpetrator of fraud so as to trigger the public disclosure bar.

*Cooper's* holding has its limits. In *U.S. ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 569-72 (10th Cir. 1995), the Tenth Circuit held that the public disclosure bar prohibited a False Claims Act lawsuit against one of nine laboratories that processed nuclear waste for the government. A GAO official testified to Congress about the misconduct at issue – "taxing" nuclear waste funds – and did so "[w]ithout naming the specific laboratories involved . . . ." *Id.* at 571. A GAO report had disclosed "taxing" by other laboratories. *Id.* at 569. In distinguishing *Cooper*, the Tenth Circuit noted that identifying individual perpetrators of fraud in the massive health insurance industry is distinct from "examining the operating procedures of nine, easily identifiable, DOE-controlled, and government-owned laboratories." *Id.* at 572.

This case falls between *Fine* and *Cooper*. Express Scripts and Medco have a finite and identified group of subsidiaries. But unlike in *Fine*, there is no indication here that either of the corporations herein named by Relator were engaged in any misconduct at all during the periods encompassed by the Pennsylvania and Tennessee lawsuits – let alone misconduct “substantially similar” to that alleged by Relator.

I thus conclude that the public disclosure bar does not require dismissal of the Relator’s claims against Accredo and Curascript. As a result, the Court need not consider whether the Relator was an “original source” of his allegations.

**III. The Relator has Properly Identified False Certifications In Connection With Most of His Claims, so the Motion to Dismiss on For Failure to Do So Is, For the Most Part, Denied.**

As discussed in *Novartis IV* and *Novartis V*, three of the four FCA subparagraphs at issue in this case – subparagraphs (a)(1)(A), (a)(1)(B), and (a)(1)(C) (counts 1a, 1b, and 1c) – require the Relator to prove either the existence of “false or fraudulent” claims or a conspiracy involving “false or fraudulent” claims. *Novartis IV*, 2014 WL 4230386, at \*3.<sup>9</sup> The parallel state statutes contain the same requirement.

In *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), the Second Circuit established the definition of a “false” claim in this Circuit: it is any claim “aimed at extracting money the government otherwise would not have paid.” *Id.* at 696. There are two types of “falsity” – *i.e.*, two reasons that the government would not pay the claim if it knew the true facts. One is factual falsity; the other is legal falsity. *See id.* at 697.

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<sup>9</sup> As discussed in *Novartis II*, proving a “reverse false claim” under FCA subparagraph (a)(1)(G) (count 1d) does not require a plaintiff to show that the defendant submitted “false” claims. *See* 2014 WL 2619014, at \*10. Count 1d is addressed below. *See infra* § IV.C.

A claim is “factually false” where the party submitting the claim supplies “an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.” *Id.*; *see also U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 812 (S.D.N.Y. 2010). In other words, the party “bills for something it did not provide.” *Kirk*, 601 F.3d at 114. No such claim is alleged here.

In contrast, a “legally false” claim is “false” because it has been tainted by some underlying statutory, regulatory, or contractual violation made in connection with that claim, which renders the claim ineligible for reimbursement. Under *Mikes*, a violation does not render a claim “false” unless (1) compliance with the underlying statute, regulation, or contract is a “precondition” to payment of the claim, and (2) a party falsely represents (or “certifies”) compliance with the provision in connection with the claim. 274 F.3d at 697-98. The *Mikes* Court distinguished between preconditions to *payment* of claims and mere conditions of *participation* in a government program; in order for a statutory violation to provide a basis for legal “falsity,” the government’s decision to reimburse the claim must be conditioned upon compliance with the underlying statute. *See id.* at 701-02. The preconditions to payment vary by government program.

*Mikes* set forth the analytical framework for the “false certification” theory of legal “falsity.” *See id.* at 697-99. Under this theory, a claim is rendered “false” (and thus, ineligible for reimbursement) where the party submitting the claim falsely “certifies” compliance with a statutory, regulatory, or contractual provision, and that compliance is a precondition to payment of the claim. *See id.* at 697-98. There are two types of false certifications: express and implied.

As the name suggests, an “express false certification” occurs when the party submitting the claim expressly and “falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.” *Id.* at 698. Generally, express certifications

arise when a government program requires participants to submit forms explicitly stating that they have complied with certain statutes. *See id.* Where the party certifying compliance is, in fact, violating the statute in question, that certification is “false.” The claims rendered legally “false” by such false certifications include all the claims connected to the underlying statutory violation.

Legal “falsity” can also arise on a theory of “implied false certification.” The implied false certification theory is “based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.” *Id.* at 699. In *Mikes*, the Second Circuit stated that this theory “is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid.” *Id.* at 700 (emphasis in original). “Liability under the Act may properly be found . . . when a defendant submits a claim for reimbursement while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant.” *Id.*

Here, the Relator argues that the claims for Novartis drugs that the pharmacies submitted during the course of the kickback schemes were rendered legally “false” by the pharmacies’ express and implied certifications of compliance with the AKS. Because those pharmacies were, in fact, engaged in a kickback scheme with Novartis, the Relator contends, those compliance certifications and the corresponding claims were “false.”

In *Novartis V*, the Court held that the Relator adequately pleaded false certifications in connection with his post-March 23, 2010 claims. *Novartis V*, 2014 WL 4370597, at \*27. After that date, the Patient Protection and Affordable Care Act (“PPACA”) amended the AKS to “expressly state[] that violating the AKS rendered claims ‘false’ under the FCA.” *Id.* That provision clearly permitted the Relator to proceed on an implied false certification theory in connection with



Medicare, Medicaid, and TRICARE claims submitted after March 23, 2010. *Id.* Accredo and Curascript did not argue otherwise, and do not do so now.

What Accredo and Curascript do argue is that the Relator has failed to identify false certifications – either express or implied – in connection with most of his claims before March 23, 2010.

**A. Medicare Part D Subcontracts Are Express Certifications**

To administer prescription drug plans under Medicare Part D, the Department of Health and Human Services (“HHS”), through its component agency, the Center for Medicare and Medicaid Services (“CMS”), contracts with private companies (“Part D plan sponsors”) to provide prescription drug benefits. Part D plan sponsors must agree to comply with “Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).” 42 C.F.R. § 423.505(h)(1).

Part D plan sponsors, in turn, enter into subcontracts with pharmacies (including those involved in the kickback scheme) to provide drugs to Medicare Part D beneficiaries. Under 42 C.F.R. §§ 423.505(i)(3)(iv), (i)(4)(iv), those subcontracts must contain language obligating the pharmacies to comply with applicable federal laws, regulations, and CMS instructions.

In *Novartis IV*, the Court held that those applicable laws include the AKS. *Novartis IV*, 2014 WL 4230386, at \*12-13. Thus, in *Novartis IV*, the Court held that the pharmacies “express[ly] certifi[ed]” compliance with the AKS “in their subcontracts with Part D plan sponsors.” *Id.* at \*13. The Court reaffirmed that holding in *Novartis V*: “the Relator has adequately alleged that all the claims the pharmacies submitted to . . . Medicare Part D during the course of the kickback scheme were rendered ‘false’ by these express certifications.” *Novartis V*, 2014 WL 4370597, at \*28.

Accredo and Curascript (but not Caremark) urge the Court to reconsider that holding, arguing that contract provisions are not express certifications.

That argument misses the mark.

The one case Accredo and Curascript cite for the proposition that contracts are not express certifications is *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370 (4th Cir. 2008). What *Wilson* actually held was that a putative relator cannot bootstrap a breach of contract claim into a claim of fraud, by asserting that each contract term is a certification that a party will comply with the contract. *Id.* at 377-38. But that is not what the Relator is attempting to do. The Relator does not argue that Accredo and Curascript falsely certified compliance with the terms of their Medicare Part D contracts in those contracts themselves. Rather, the Relator argues that Accredo and Curascript violated the AKS, yet certified compliance with the AKS in contracts that specified (as each contract between Plan D sponsors and pharmacies *must* specify) “that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions” including the AKS. 42 C.F.R. § 423.505(i)(4)(iv); *see id.* § 423.505(i)(3)(iv).

**B. Relator Has Not Identified Any False Certification In Connection with TRICARE**

In *Novartis V*, the Court held that the Relator had failed to adequately plead either express or implied false certifications in connection with TRICARE for claims submitted before March 23, 2010. *Novartis V*, 2014 WL 4370597, at \*29-30. That dismissal was without prejudice, *id.* at 30.

The Relator’s Third Amended Complaint fails to correct this deficiency. The Relator points to 32 C.F.R. § 199.9(a)(4) (which is incorrectly cited in the Relator’s Complaint). That regulation provides that “Providers seeking payment from the Federal Government through programs such as [TRICARE] have a duty to familiarize themselves with, and comply with, the program

requirements.” Beyond that regulation, the Relator notes only that providers who commit fraud – including giving or receiving kickbacks – can be excluded from TRICARE. *See* 32 C.F.R. § 199.9(c)(12).

The Court already held in *Novartis V* that § 199.9(c)(12) does not expressly require compliance with the AKS as a condition of payment. Thus, it does not allow the Relator to plead an implied certification claim.

Paragraph 199.9(a)(4) also does not require AKS compliance as a condition of payment. A “duty to familiarize” with program requirements comes nowhere close to establishing a condition of payment. Indeed, it does not even establish a condition of participation or, really, any condition at all. That regulation cannot support an implied certification claim. The Relator’s Complaint does not mention any contracts or provider agreements which would provide a basis for an express certification claim with respect to TRICARE.

The Relator does not discuss TRICARE in his opposition to Accredo’s and Curascript’s motion. He does not explain any basis – express or implied certification – for allowing his TRICARE claims to go forward. Count 1 of the Relator’s Complaint is therefore dismissed with prejudice insofar as it concerns claims submitted to TRICARE before March 23, 2010.

**C. The Relator Has Adequately Pleaded Express False Certifications In Connection With Most State Medicaid Programs**

In *Novartis V*, the Court held that “the Relator . . . failed to plead any express or implied false certifications that rendered the claims submitted to the state Medicaid programs . . . ‘false.’” 2014 WL 4370597, at \*29. The only exceptions were the state Medicaid programs of Florida, Illinois, Michigan, and New York. *Id.* With respect to those programs, the Relator pleaded express certifications in detail, and the Defendants did not move to dismiss claims brought under those

programs. Accredo and Curascript now concede that they waived any challenge to those certifications. Accredo & Curascript Mem. at 14 n.6.

In his Third Amended Complaint, the Relator pleads false certifications in connection with state Medicaid programs in greater detail. Accredo and Curascript concede that the Relator has adequately pleaded false express certifications in connection with Arizona, New Jersey, and Maine Medicaid programs, and false implied certifications in connection with California and South Carolina Medicaid programs.

Conversely, the Relator concedes that he has failed to allege any false certifications, express or implied, in connection with North Dakota's Medicaid program.

That leaves 40 remaining states plus the District of Columbia still in dispute.<sup>10</sup> The Relator incorporates by reference the allegations in the Government's Complaint with respect to 20 of those states and the District of Columbia, (Compl. ¶ 50), and he separately alleges express certifications with respect to the remaining 20 states in his Third Amended Complaint. (Compl. ¶¶ 52-72.) Both the Government's and the Relator's complaints allege that the defendants expressly and falsely certified compliance with the AKS in Medicaid provider enrollment agreements, in which participants promise to abide by applicable state and federal regulations.

Accredo and Curascript make only one argument challenging these newly pleaded false certifications. They argue that the certifications contained in state Medicaid provider enrollment agreements are forward-looking promises, rather than affirmative representations of fact. For example, the Louisiana provider agreement requires providers to certify that they "will conduct

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<sup>10</sup> Those states are Alabama, Alaska, Arkansas, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, Oklahoma, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.



their activities . . . .” in accordance with applicable laws. (Compl. ¶ 59.) Those sorts of forward-looking promises, according to Accredo and Curascript, cannot be “false”, and therefore cannot be the basis of “false certifications” under *Mikes*.

The first problem with this argument is that it contradicts the Court’s holdings that the Government and the Relator had adequately alleged express false certifications with respect to Medicare Part B. Pharmacies participating in Medicare Part B are required to enter into a provider agreement on CMS form 855S, which reads in part:

I agree to abide by the Social Security Act and all applicable Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare. *Novartis IV*, 2014 WL 4230386, at \*11.

In *Novartis IV*, the Court stated that “The language in CMS Form 855S is clearly sufficient to constitute an express certification of compliance with the AKS.” *Id.* I concluded that “that a party’s submission of . . . CMS Form 855S renders a claim ‘false,’ where the party was allegedly violating the AKS in connection with the underlying transaction that is the subject of that claim.” *Id.* at \*12. The language on form 855S is quite similar to the language contained in the state Medicaid provider agreements described in the Relator’s Complaint. Its language – “I agree to abide” – does not predict future behaviors; it obligates the provider to behave in a certain manner.

Accredo and Curascript cite no case law supporting their position. Admittedly, a few district court opinions (not from this district) have held that forward-looking promises cannot constitute a false certification. But as Judge Ellison of the Southern District of Texas recently put it, “The Court finds the legion of cases endorsing the use of enrollment agreements [in False Claims Act cases] more persuasive than the three Northern District of Illinois cases that

Defendants cite for the proposition that forward-looking promises can never qualify as false certifications.” *U.S. ex rel. Ruscher v. Omnicare, Inc.*, No. 08 Civ. 3396, 2014 WL 2618158, at \*20 (S.D. Tex. June 12, 2014) *on reconsideration in part sub nom. Ruscher v. Omnicare Inc.*, 2014 WL 4388726 (S.D. Tex. Sept. 5, 2014). Furthermore, as far as *this* Court is concerned, the flaw in the Northern District of Illinois cases is describing the undertaking of a blinding obligation as a “forward looking” promise. The law relating to “forward looking” statements grew up in field of servitudes law, to insulate *predictions* from the reach of anti-fraud statutes. These provider agreements are not prediction – they are not hopes or expectations. They are contractual obligations.

I cannot see anything in *Mikes* or other false certification cases that would compel a different result. Pharmacies participating in Medicare Part B stated that they would comply with applicable laws, including the AKS. Those certifications were false because the pharmacies did not in fact comply with the AKS. That is, if the Government knew that the Pharmacy Defendants were not complying with the AKS, it would not have paid them. The state Medicaid provider agreements described in the Complaint required participants to make a comparable promise. That promise was false because the pharmacies violated the AKS. Accredo’s and Curascript’s motion to dismiss for failure to plead false certifications is therefore denied.

#### **IV. The Relator Has Pleaded Fraud with Particularity**

Rule 9(b) requires that a party “alleging fraud or mistake . . . state with particularity the circumstances constituting fraud or mistake.” Claims brought under False Claims Act sound in fraud and are therefore subject to Rule 9(b)’s heightened pleading requirements. *Novartis I*, 23 F. Supp. 3d at 251-52.

In general, to comply with Rule 9(b), a complaint must “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements

were made, and (4) explain why the statements were fraudulent.” *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004) (internal citations and quotation marks omitted). “In other words, ‘Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.’” *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04 Civ. 704, 2009 WL 1456582, at \*4 (E.D.N.Y. May 22, 2009) (quoting *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)).

In *Novartis I*, the Court held that claims brought under subparagraphs (a)(1)(A) and (a)(1)(B) of the False Claims Act (counts 1a and 1b of the Relator’s Complaint) require the Relator to show two falsehoods: (1) the existence of a fraudulent scheme perpetrated by a plaintiff, and (2) the submission of false claims to the government. Both falsehoods must be pled with particularity under Rule 9(b). *Novartis I*, 23 F. Supp. 3d at 252-53. Accordingly, a plaintiff “cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted.” *Polansky*, 2009 WL 1456582, at \*5. He must also plead the “claim” submission element with particularity.

How does a plaintiff plead the submission of a false claim with particularity? *Novartis I* rejected the Government’s argument that it could satisfy Rule 9(b) by “alleg[ing] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” 23 F. Supp. 3d at 254-55 (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). Adopting the Government’s proposed rule would fail to fulfill Rule 9(b)’s purposes: “provid[ing] enough detail for a defendant to be able to reasonably identify particular claims that are allegedly false” and “weed[ing] out FCA claims

brought by plaintiffs who are merely speculating that false claims might have been submitted to the government.” *Id.* at 256.

The better rule was set forth by the First Circuit in *United States ex rel. Karvelas v. Melrose–Wakefield Hospital*, 360 F.3d 220 (1st Cir. 2004): a plaintiff must “identify particular false claims for payment that were submitted to the government.” *Id.* at 232. To satisfy Rule 9(b) then, a plaintiff must “both (1) identify which of the claims submitted were ‘false’ and (2) provide factual support (as opposed to mere speculation) for [its] assertions that claims were actually submitted to a government program.” *Novartis I*, 23 F. Supp. 3d at 258. Plaintiffs can satisfy the second prong – and provide factual support – in one of two ways: “(1) providing sufficient identifying information about all the false claims, or (2) providing example false claims.” *Id.*

The Court previously dismissed counts 1a and 1b of the Relator’s Complaint with respect to Gleevac, Tasigna, and TOBI because the Relator’s Second Amended Complaint failed to satisfy Rule 9(b). I explained that although the Relator’s Complaint “ma[d]e[] clear which false claims are at issue – all claims for Novartis drugs submitted by each pharmacy during the kickback scheme – the Relator d[id] not provide any factual basis to support his assertion that Novartis actually caused any pharmacy to submit claims for Gleevac, Tasigna, or TOBI to the government.” *Novartis II*, 2014 WL 2619014, at \*8.

Given the opportunity to replead, the Relator has included dozens of sample claims in his Third Amended Complaint. (Compl. ¶ 158.) Each claim includes a claim number, drug and quantity, date, the pharmacy submitting the claim, and the program under the claim was billed. For example, claim number 114005210800, submitted by Curascript, “billed California Medicaid \$4,513.04 for 280 units of TOBI 300mg/5 ML Solution . . . on March 4, 2011.” (Compl. ¶ 158). As another example, claim number 201135050045484 “billed New Jersey Medicaid \$15,122.93



for 112 units of Tasigna, 150 mg capsules . . . on December 16, 2011.” (Compl. ¶ 158). The sample claims listed in the Complaint include claims for each of the three drugs billed by each of the three Pharmacy Defendants. But the claims do not cover all the government programs at issue. In particular, the Relator has not provided any example claims submitted to Medicare Part B, Medicare Part D, or TRICARE.

The Pharmacy Defendants have once again moved to dismiss counts 1a and 1b and analogous state law claims with respect to the Gleevac, Tasigna, and TOBI schemes. First, they argue that the Relator improperly obtained the example claims listed in the Complaint, and so is not entitled to plead in reliance on those claims. Second, they argue that the sample claims are not sufficiently representative of the Relator’s claims with respect to Medicare and TRICARE to satisfy Rule 9(b).

**A. There Is No Convincing Evidence That Relator Obtained Data In Violation of HIPAA Or Through Undisclosed Formal Discovery**

Caremark argues that the Relator should not be permitted to amend his Complaint by including sample state Medicaid claims because he either (1) obtained those claims data informally, in which case he violated the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), Pub. L. No. 104-191, 110 Stat. 1936, or (2) he obtained those data through undisclosed formal discovery in violation of FED. R. CIV. P. 5(a)(1)(C) and 45(a)(4).

Caremark has not made its case.

That Relator affirmatively states that he did not use formal discovery to obtain the information, but states that various “state entities” “voluntarily provided” the claims data included in his Complaint. Relator Opp. at 15-16. Caremark has presented no evidence to the contrary, and without evidence I will not assume that Relator took “undisclosed formal discovery” in violation of the Federal Rules of Civil Procedure.

That leaves the alleged HIPAA violation. Caremark claims that the Relator must have obtained healthcare data containing “[i]ndividually identifiable health information,” which – if it was obtained without formal discovery (or from an individual who can waive his own HIPAA rights) – would violate HIPAA. *See* 45 C.F.R. §§ 160.103, 164.512(e)(1)(ii). The only support offered for Caremark’s claim, however, is negative implication from the Relator’s Complaint, which states, “To protect patient privacy, Relator includes no individually-identifiable health information herein.” (Compl. ¶ 158.) Caremark claims that there would be no need to add this caveat unless Relator possessed individually-identifiable health care information, in violation of HIPAA.

The Relator denies Caremark’s inference from the Complaint. Caremark is “simply wrong” to “say that Relator *possessed* such information.” Relator Opp. at 15.

Caremark’s inference is not unreasonable one, but it is also not the only way to read the Complaint. Given the sensitivity of patient information, it is also reasonable to believe that the Relator included his statement in an abundance of caution, rather to imply that he had obtained information he should not have received under HIPAA.

Relator will have to provide discovery under oath about how he obtained the information that Caremark contends was obtained in violation of HIPAA. If HIPAA violations are discovered, we will revisit this issue of sanctions. At present, I will not dismiss the complaint on the ground that the particularizing information was obtained in violation of law.

**B. The Relator’s Sample Claims Are Sufficiently Representative of Claims Arising from the Fraudulent Scheme To Satisfy Rule 9(b)**

The Pharmacy Defendants also argue counts 1a and 1b should be dismissed insofar as they concern payment claims for Gleevac, Tasigna, or TOBI submitted Medicare and TRICARE,

because the sample claims included in the Relator's Complaint do not provide factual support for the Relator's allegation that false claims were actually submitted to those programs.

It is important to clarify the scope of this argument. As I explained in *Novartis II*, the existence of example claims does not affect the Relator's claims under subparagraph (a)(1)(C) of the False Claims Act (count 1c), "because no false claim need have been submitted for [subparagraph] (a)(1)(C) liability to attach." *Novartis I*, 23 F. Supp. 3d at 268. Nor does the Pharmacy Defendant's argument concern the Exjade or Myfortic schemes. With respect to those schemes, the Relator incorporates the Government's Complaint by reference. I previously held that the Government's allegations had satisfied Rule 9(b) for those two drugs. *Id.* at 263-67.

What the Pharmacy Defendants do argue is that the Relator's sample claims are not sufficiently "representative of those arising from the fraudulent scheme[s]" under Medicare, TRICARE, or independent state healthcare programs (and then only for counts 1a and 1b). *Id.* at 259; *see* Caremark Mem. at 15-16. Curascript and Accredo also argue that the sample claims are not sufficiently representative to satisfy Rule 9(b) for state Medicaid programs other than those for which sample claims are listed in the Complaint. Accredo & Curascript Mem. at 19-20.

In support of this argument, the Pharmacy Defendants cite *U.S. ex rel. Mooney v. Americare, Inc.*, No. 06 Civ. 1806, 2013 WL 1346022, at \*6-7 & n.6 (E.D.N.Y. Apr. 3, 2013), in which the relator alleged that the defendants fraudulently altered medical records to seek greater reimbursement from both Medicaid and Medicare. *Id.* at \*6. In support of that claim, the defendants submitted 12 sample claims under Medicare, but not Medicaid. *Id.* The Court dismissed the relator's claims as they related to Medicaid, because she "failed to allege any specific claims relating to Medicaid" and thus "failed to satisfy the heightened pleading standard as to Medicaid claims allegedly made pursuant to the fraudulent alteration scheme." *Id.*

I conclude that the Relator has satisfied Rule 9(b)'s requirement that he plead "the submission of false claims . . . with a high degree of particularity." *Novartis I*, 23 F. Supp. 3d at 256.

First, the requirement that a plaintiff provide "representative" sample claims does not mean that a plaintiff must provide sample claims from each program on behalf of which he has brought suit. As I explained in *Novartis I*, there is no mandatory "checklist" of information a plaintiff must provide to satisfy Rule 9(b). *Id.* (quoting *Karvelas*, 360 F.3d at 232). Yet the Pharmacy Defendants have demanded just such a checklist here; they ask that the Relator submit information (in the form of one or more claims) about each government program. There is no logical stopping point for such an argument. The Pharmacy Defendants could just as easily demand that the Relator provide sample claims for each drug with respect to each program during each year of the kickback scheme. Rule 9(b) is simply not that rigid in False Claims Act cases.

The Pharmacy Defendants might reply that sample claims need not cover every possible permutation of timing, drug, program and pharmacy, so long as the sample claims cover each program under which the Relator brings suit. But that is hardly a principled distinction. If claims submitted by one pharmacy or for one drug provide factual support for the submission of false claims by a different pharmacy or for a different drug, then the same reasoning should hold across programs.

Second, the sample claims listed in the Complaint satisfy Rule 9(b)'s purpose because they "provid[e] a factual basis . . . to support the plaintiff's assertion that claims were actually submitted to" Medicare and TRICARE. *Novartis II*, 2014 WL 2619014, at \*5. The sample claims show that false claims were submitted to a half-dozen state Medicaid programs for Gleevac, Tasigna, and TOBI. They are direct evidence of the submission of false claims. The allegations in the



Government's Complaint, which the Relator incorporates by reference, provide comparable direct evidence of false claims submitted to Medicare (but for other drugs).

Viewing those facts together, it is reasonable to believe that false claims for Gleevac, Tasigna, and TOBI were submitted to Medicare and TRICARE. Each of those drugs and each of those programs are shown in the Complaint to be part of a fraudulent scheme perpetrated by the defendants. Combining those falsehoods requires no inferential leap. It is a common-sense conclusion from the facts alleged in the Complaint.

The modest inferential step required to conclude that false claims for Gleevac, Tasigna, and TOBI were submitted to Medicare, is not the sort of inference that Rule 9(b) precludes. What a plaintiff cannot do is allege the existence of a fraudulent scheme and ask the Court to infer that – because of standard practices – the fraudulent claims resulting from the scheme must have been submitted to the government in “due course.” *Novartis I*, 23 F. Supp. 3d at 254. But that is not what Relator has done. Relator argues that, from the submission of a few sample fraudulent claims, one can infer the submission of other similar claims as part of the same fraudulent scheme. Such an assumption does not expose the pharmacy defendants to baseless or speculative fraud allegations – the problem Rule 9(b) is intended to protect against.

### **C. The Motion to Dismiss Relator's Reverse FCA Claims Is Denied**

All three defendants argue that the Relator's claims under subparagraph (a)(1)(G) (count 1d) of the False Claims Act – that is, his “reverse” FCA claims – must be dismissed because they duplicate his claims under subparagraphs (a)(1)(A)-(C) (counts 1a-1c).

For the reasons stated above, I am not dismissing counts 1a-1c. The Pharmacy Defendants have not argued for dismissal of count 1d except for the same reasons that they argue (unpersuasively) for dismissing the other FCA counts. Thus, I will not dismiss count 1d.

The Relator will not, of course, be able to obtain double recovery for the same fraudulent claims. Nor will he be able to recover under count 1d based on an obligation to repay money that was not in fact obtained based on a false claim.

## CONCLUSION

For the foregoing reasons, Caremark's motion to dismiss is **GRANTED IN PART** and **DENIED IN PART**. Curascript and Accredo's motion to dismiss is **GRANTED IN PART** and **DENIED IN PART** as described above.

The Relator's claims against Caremark under the False Claims Acts of California, Connecticut, Delaware, the District of Columbia, Florida, Illinois, Louisiana, Massachusetts, Michigan, Nevada, New Mexico, North Carolina, Tennessee, Texas, and Virginia (counts 2, 4-7, 10, 12, 14-15, 18, 20, 22, and 25-27) are dismissed insofar as they concern payment claims submitted prior to March 23, 2010. The Relator's claims against all three Pharmacy Defendants are dismissed insofar as they concern claims submitted to TRICARE prior to March 23, 2010. The motions to dismiss are otherwise denied.

Still pending are claims 1a, 1b, 1c, and 1d as against Caremark, insofar as they concern claims submitted to Medicare Part B, Medicare Part D, TRICARE, and state and District of Columbia Medicaid programs (other than North Dakota) after March 23, 2010. Counts 2, 4-7, 10, 12, 14-15, 18, 20, 22, and 25-27 as against Caremark remain for claims submitted to Medicaid programs after March 23, 2010. Counts 3, 8-9, 11, 13, 16-17, 19, 21, 23-24, and 28 as against Caremark remain for the entire period of the alleged kickback scheme.

All claims remain pending against Accredo and Curascript except counts 1a and 1b insofar as they concern claims submitted to TRICARE prior to March 23, 2010.

The Clerk of the Court is directed to remove Docket #275, and Docket #277 from the Court's list of pending motions. The Clerk of the Court is also directed to remove Docket #236 (the Pharmacy Defendants' previous motion to dismiss count 1d of the Relator's complaint) from the Court's list of pending motions. That motion was denied by the Court's memorandum endorsement of September 29, 2014 (Docket #263).

Dated: January 6, 2015

A handwritten signature in black ink, appearing to read "Peter M. Mc". The signature is written in a cursive, flowing style.

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U.S.D.J.

BY ECF TO ALL COUNSEL